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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,695	02/04/2004	Paul D. Hanke	040049	4373

45453 7590 06/02/2006

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PITTSBURGH, PA 15219

EXAMINER

KIM, ALEXANDER D

ART UNIT PAPER NUMBER

1656

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/771,695

Applicant(s)

HANKE ET AL.

Examiner

Alexander D. Kim

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/15/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09/02/2004, 02/04/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09/12/2005</u> . | 6) <input checked="" type="checkbox"/> Other: <u>SEQ Alignment</u> . |

DETAILED ACTION

Application Status

1. The instant action is in response to Applicants' election filed on 04/25/2006.
Claims 19-24 are pending in the instant application.

Election

2. Applicant's election without traverse of Group IV, Claims 19-24, is acknowledged.
Claims 19-24 are pending in the instant application. Claims 1-18 and 25-32 are cancelled by the amendment filed on 04/25/2006.

Priority

3. Applicant's claim for the benefit of a divisional application of prior-filed U.S. applications 09/722,441 (filed on 11/28/2000), which claims benefit of provisional application 60/184,130 (filed on 02/22/2000) and 60/173,707 (filed on 12/30/1999) under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Inventorship

4. In view of the papers filed 05/15/2006, the inventorship in this nonprovisional application has been changed by the deletion of Corey M. Crafton and P. John Rayapati.

K. Kew

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Information Disclosure Statement

5. The information disclosure statement (IDS) filed on 09/12/2005 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Objections to the Specification

6. The specification is objected to because of the following informalities:

a. The specification is objected to because the title is not descriptive of the elected species to which the claims have been limited to herein. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The examiner suggests the following new title:

---A polynucleotide encoding a truncated ORF2 from *Corynebacterium*---

b. The Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion

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of the gene (orf2), full name of the encoded protein (hypothetical protein) and the source of the gene (*Corynebacterium glutamicum*) for completeness.

Appropriate correction and/or clarification are required.

c. In Figure 24, the capital letter I with parenthesis "(I)" at the end of the protein sequence lacks description in the specification or in the drawing.

d. In Figure 22, the construction of plasmid pDElia2_{FC5}-KDBHL is illustrated as if pDElia2_{FC5}-KDBHL is directly derived from pDElia2_{FC5}. The line is missing to indicate the Not I-Pme I fragment of pFC3-KDBHL was ligated with pDElia2_{FC5}.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 19-22 and 24 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to an isolated polynucleotide that encodes a

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polypeptide sequence having at least 95% identical to SEQ ID NO: 19 and a method for selecting a transformed *Corynebacterium* with the said nucleotide.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. (*Enzo Biochem* 63 USPQ2d 1609 (CAFC 2002)).

The instant specification teaches an isolated polynucleotide containing the coding region for SEQ ID NO: 19. The breath of claim includes all polynucleotide encoding any protein having at least 95% identical to SEQ ID NO: 19, a truncated ORF2 protein encoded by SEQ ID NO: 18. The instant specification does not disclose specific activity of ORF2 polypeptide. The function of full length ORF2 is unknown according to the prior art. Therefore, correlations between a structure and a function cannot be

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described by the instant specification or the prior art. The instant specification teaches only about N-terminal half of ORF2 thus makes more difficult to have a proper function if there is any. Because the specification does not teach any method of calculating homology, the clear scope of claim cannot be identified. Because there are neither a known function nor any functional assay to represent genus claim of nucleotides, one skilled in the art would be unable to make and use the claimed invention by correlating the structure and/or the function.

8. Claims 19-22 and 24 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, while being enabling for the host cell NRRL B30360, which is transformed with vector pDElia2_{FC5}-KDBHL, however, does not reasonably provide enablement for any nucleotide encoding a polypeptide with at least 95% identity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to

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make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The nature of invention is drawn to an isolated nucleic acid encoding polypeptide comprising sequence of SEQ ID NO: 19. The breadth of Claims 19-22 and 24 are broad as to encompass all nucleic acid encoding a protein having sequence of at least 95% homology compared to SEQ ID NO: 19, which may be enabled for only replacing the truncated ORF2 segment in vector pDElia2_{FC5}-KDBHL and transform into *Corynebacterium* for lysine production as taught by the instant specification. However, the specification and prior arts do not teach anything else for any enablement of the claimed nucleotides. The specification provides only a single working example of a nucleotide of SEQ ID: 18, which may be encoding a polypeptide containing SEQ ID NO: 19. Because the direction or guidance about the specific functional assay is unknown and without knowing what activity to measure, it is unpredictable for a nucleotide to encode SEQ ID NO: 19 homologue with at least 95% identity to have any contribution for an enablement other than the one example disclosed in the instant specification. By

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all the reasons above, the quantity of experimentation needed to make or use the invention claimed based on the content of the disclosure is very high thus requiring undue experimentation for a skilled artisan to make and use the entire scope of the claimed invention.

9. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, enabling deposit, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel biological material, specifically the host cell deposited as NRRL B30360. Since the biological material are essential to such an invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 USC 112 §1st may be satisfied by a deposit of the biological materials.

The transmittal letter (filed on Feb. 4, 2004) discloses deposited the biological materials according to the Budapest Treaty. However, the deposit requirement is not fulfilled because the following requirement has to be satisfied: The biological material NRRL B30360 is not included in the letter. This Office action reminds applicants that an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific of record over his or her

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signature and registration number, stating that the specific biological materials will be irrevocable and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

Applicant's attentions is directed to MPEP section 2400 in general, and specifically to 2411.05, as well as to 37 CFR 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, "the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination". The specification should be amended to include this information, however, applicant is cautioned to avoid entry of new matter into the specification by adding any other information.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Pisabarro et al. (1993 May, Journal of Bacteriology, Vol. 175, pp. 2743-2749 as cited in IDS).

Pisabarro et al. teach a gene *orf2* sequence 100% identical to a polynucleotide sequence of SEQ ID NO: 18 and it encodes polypeptide 100% identical to polypeptide sequence of SEQ ID NO: 19 (see SEQ Alignment in the attachment).

Pissabarro et al. teach vectors pULAP301 (Figure 2, pp. 2745), pULAP2 (Figure 3, pp. 2748) carrying an orf2 gene and an E. coli host carrying "several constructions carrying dapA, dapB, ORF2, and combinations of them" (see top left column in pp. 2748). Thus DNA from Pisabarro et al. meets all the limitations of Claims 19-22.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pisabarro et al. (1993 May, Journal of Bacteriology, Vol. 175, pp. 2743-2749 as cited in IDS) in view of Serworld-David et al (1987, Proc. Natl. Acad. Sci. USA, Vol. 84, pp. 4964-4968).

Pisabarro et al. teach as described above.

Pisabarro et al. do not teach transforming a *Corynebacterium* with the vector encoding a SEQ ID NO: 19.

Serwold-Davis et al. teach a shuttle vector able to transform both *Corynebacterium* species and *E. coli*.

Pisabarro et al. suggest that "it is likely that ORF2 is also translated in corynebacteria" in lysine biosynthesis (see bottom left column, last paragraph on pp.

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2748). It would have been obvious to one of ordinary skill in the art at the time the invention was made to transform a *Corynebacterium* with the orf2 gene as taught by Pisabarro et al. for a production of L-lysine. Accordingly, the invention taken as a whole is *prima facie* obvious.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to transform the gene of Pisabarro et al. into *Corynebacterium* species using the shuttle vector of Serwold-Davis et al. with a reasonable expectation of success for the transformation of *Corynebacterium* species with polynucleotide molecules of claim 19. The motivation to do so is provided by Pisabarro et al. who suggest "it is likely that ORF2 is also translated in corynebacteria" in lysine biosynthesis (see bottom left column, last paragraph on pp. 2748). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 19-22 and 24 are rejected on the ground of nonstatutory double patenting over claims 11-13 and 48 of U. S. Patent No. 6,927,046 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The Claim 11 from Patent No. 6,927,046 discloses an isolated polynucleotide encoding a full length of ORF2 thus it overlaps the scope of instant Claims 19 and 20. Claims 12 and 13 from Patent No. 6,927,046 disclose a vector and host cell containing the vector, respectively, which contains polynucleotide encoding a full length of ORF2 thus they overlaps the scope of instant Claims 20 and 21, respectively. The Claim 48 from Patent No. 6,927,046 discloses a method for transforming a *Corynebacterium* species host cell having vector with full length of ORF2 thus it overlaps the scope of the instant Claim 24.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application, which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

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Conclusion

13. Claims 46-64 are rejected for the reasons identified in the numbered sections of the Office Action. Applicants must respond to the objections/rejections in each of the numbered sections in the Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alexander Kim
May 19, 2006


KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER

SEQ Alignment
10/771695

RESULT 1

THYX_CORGL

ID THYX_CORGL STANDARD; PRT; 250 AA.

AC P40111;

DT 01-FEB-1995 (Rel. 31, Created)

DT 28-FEB-2003 (Rel. 41, Last sequence update)

DT 10-MAY-2005 (Rel. 47, Last annotation update)

DE Thymidylate synthase thyX (EC 2.1.1.148) (TS) (TSase).

GN Name=thyX; OrderedLocusNames=Cgl1972, cg2162;

OS Corynebacterium glutamicum (Brevibacterium flavum).

OC Bacteria; Actinobacteria; Actinobacteridae; Actinomycetales;

OC Corynebacterineae; Corynebacteriaceae; Corynebacterium.

OX NCBI_TaxID=1718;

RN [1]

RP NUCLEOTIDE SEQUENCE.

RC STRAIN=ATCC 13869;

RX MEDLINE=93239702; PubMed=8478336;

RA Pisabarro A., Malumbres M., Mateos L.M., Oguiza J.A., Martin J.F.;

RT "A cluster of three genes (dapA, orf2, and dapB) of Brevibacterium

RT lactofermentum encodes dihydrodipicolinate synthase,

RT dihydrodipicolinate reductase, and a third polypeptide of unknown

RT function.";

RL J. Bacteriol. 175:2743-2749(1993).

RN [2]

RP NUCLEOTIDE SEQUENCE [LARGE SCALE GENOMIC DNA].

RC STRAIN=ATCC 13032 / DSM 20300 / NCIB 10025;

RA Nakagawa S.;

RT "Complete genomic sequence of Corynebacterium glutamicum ATCC 13032.";

RL Submitted (MAY-2002) to the EMBL/GenBank/DDBJ databases.

RN [3]

RP NUCLEOTIDE SEQUENCE [LARGE SCALE GENOMIC DNA].

RC STRAIN=ATCC 13032 / DSM 20300 / NCIB 10025;

RX PubMed=12948626; DOI=10.1016/S0168-1656(03)00154-8;

RA Kalinowski J., Bathe B., Bartels D., Bischoff N., Bott M.,

RA Burkovski A., Dusch N., Eggeling L., Eikmanns B.J., Gaigalat L.,

RA Goesmann A., Hartmann M., Huthmacher K., Kraemer R., Linke B.,

RA McHardy A.C., Meyer F., Moeckel B., Pfefferle W., Puehler A.,

RA Rey D.A., Rueckert C., Rupp O., Sahm H., Wendisch V.F., Wiegraebe I.,

RA Tauch A.;

RT "The complete Corynebacterium glutamicum ATCC 13032 genome sequence

RT and its impact on the production of L-aspartate-derived amino acids

RT and vitamins.";

RL J. Biotechnol. 104:5-25(2003).

CC -!- FUNCTION: Catalyzes the formation of dTMP and tetrahydrofolate

CC from dUMP and methylenetetrahydrofolate (By similarity).

CC -!- CATALYTIC ACTIVITY: 5,10-methylenetetrahydrofolate + dUMP +

CC FADH(2) = dTMP + tetrahydrofolate + FAD.

CC -!- COFACTOR: Binds 1 FAD per subunit (By similarity).

CC -!- SUBUNIT: Homotetramer (By similarity).

CC -!- SIMILARITY: Belongs to the thymidylate synthase thyX family.

CC

CC This Swiss-Prot entry is copyright. It is produced through a
collaboration

CC between the Swiss Institute of Bioinformatics and the EMBL outstation

-

CC the European Bioinformatics Institute. There are no restrictions on
its

CC use as long as its content is in no way modified and this statement is

not

CC removed.

Ref

→


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